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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,451	06/04/2007	Ernestine Lee	08940.0038	9377

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,451	LEE ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1, 5-6, 8, 13,16-18, 23, 30-32, 34-36, 41, 44, 49, 52, 53, 55, 64, 70, 74, 76, 78 and 80

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1, 5-6, 8, 13,16-18, 23, 30-32, 34-36, 41, 44, 49, 52, 53, 55, 64, 70, 74, 76, 78 and 80

DETAILED ACTION

Claims 1, 5-6, 8, 13,16-18, 23, 30-32, 34-36, 41, 44, 49, 52, 53, 55, 64, 70, 74, 76, 78 and 80 are currenlty pending.

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1, 5, 6, 18, 23, 30, 32, 34 and 80, drawn **to an isolated nucleic acid molecule** comprising a first polynucleotide, a vector comprising said nucleic acid molecule, a host cell comprising said nucleic acid molecule and pharmaceutical composition comprising said nucleic acid molecule.

II. Claims 8, 13, 16, 17, 31 and 41, drawn to **an isolated polypeptide** comprising a first amino acid sequence and pharmaceutical composition comprising said polypeptide.

III. Claim 35, drawn to **a method of producing a recombinant host cell** comprising providing a vector comprising a nucleic acid molecule and allowing a cell to come into contact with the vector to form a recombinant host cell transfected with the nucleic acid molecule.

IV. Claim 36, drawn to **a method of producing a polypeptide** providing a nucleic acid and expressing the nucleic acid molecule in an expression system to produce a polypeptide..

V. Claim 44, drawn to an antibody specifically recognizing, binding to, and/or modulating the biological activity of a polypeptide.

VI. Claim 49, drawn **a fusion molecule** comprising a first polypeptide that comprises an amino acid sequence and a second polypeptide that comprises an amino acid sequence of a fusion partner.

VII. Claim 52, drawn to **a method of determining the presence of a nucleic acid molecule** comprising: providing a complement to the nucleic acid molecule; allowing the molecule to interact with the sample; and determining whether interaction has occurred.

VIII. Claim 53, drawn **a method of determining the presence of polypeptide** in a sample, comprising: providing an antibody that specifically binds to or interfere with the activity of the polypeptide; allowing the antibody to interact with the polypeptide in the sample, if any; and determining whether interaction has occurred.

IX. Claim 55, drawn to **a method of determining the presence of a specific antibody** to a polypeptide of claim 8 in a sample, comprising: providing the polypeptide; allowing the polypeptide to interact with a specific antibody in the sample, if present; and determining whether interaction has occurred.

X. Claim 64, drawn to an *in vivo* **method for treating a tumor** in a subject comprising: providing a pharmaceutical composition of comprising a polypeptide; and administering the composition to the subject.

XI. Claims 70, 74, 76 and 78, drawn to an *in vivo* **method of treating a tumor** in a subject comprising: providing a first composition comprising a pharmaceutical composition comprising; (b) providing a second composition comprising a different anti-cancer agent, an agent effective in treating an immune disease, an agent effective in treating a

metabolic disease or an agent effective in treating a degenerative disease; and

administering the first and second compositions to the subject.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-XI appears to be that they all relate to novel polynucleotides, related polypeptides related nucleic acid and polypeptide compositions corresponding to novel human cDNA clones useful in treating proliferative disorders, e.g., cancers, and inflammatory, immune, bacterial, and viral disorders. However, prior art has taught human cDNA clones including the polynucleotide sequences of AAA39052 to AAA39088 which encode the human secreted proteins given in AAB08891 to AAB08984 which are useful for treating disorders of the immune system, hyperproliferative disorders, infectious disease and

others (Ruben et al., W0200017222 , March 30, 2000, of record). Therefore, the technical feature linking the invention of Groups I-XI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Group I drawn to an isolated nucleic acid molecule are structurally and functionally different from inventions of Groups II drawn an isolated polypeptide comprising amino acid sequences as the result of comprising either polynucleotides or polypeptides which require separate searches; they are not obvious variants and deemed patentably distinct for the following reasons: polynucleotides, which are composed of purine and pyrimidine units and polypeptides/proteins, which are composed of amino acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Additionally, because of the degeneracy of the genetic code, different nucleotide sequences can encode the same polypeptide sequence. Hence, the information provided by a polynucleotide of Groups I can be used to make a materially different polypeptide than that of Groups I. Moreover, inventions of Group V drawn to antibodies include unique technical features that are not shared by the inventions of Groups I-IV or VI-XI. For example, antibodies are proteins made of two large heavy chains H and two small light chains L: additionally, antibodies are produced by B cells. Furthermore, inventions of Groups III, IV,VII, VIII and IX are drawn to in *vitro* methods whereas inventions of Groups X and XI are drawn to

in *vivo* therapy methods comprising, for example, administration to a subject for treatment of tumor providing a pharmaceutical composition, i.e., Group X, or providing a pharmaceutical composition, a second composition, and the first and second compositions to the subject, i.e., Group XI, which steps are not required by the active steps of Groups III, IV,VII, VIII and IX. In addition, each of Groups III, IV, VII, VIII and IX require distinct active methods steps no required as being disclosed by the others. For example, Group VII drawn to a method of determining the presence of a nucleic acid molecule requires providing a complement a nucleic acid molecule to determine interaction which step is not required by active steps of Groups III, IV, VIII and IX.

Thus, the claims in Groups I-XI are drawn to distinct methods that utilize distinct steps, requiring non-coextensive search and examination. Hence, it follows from the preceding analysis that the claimed inventions listed as Groups I-XI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

In addition, if any of inventions I-XI are elected, a **further restriction** is required between compositions and methods which involve the isolated nucleic acid molecules selected from the group consisting of **SEQ ID NOs. 1-187, and 375-484** and the isolated nucleic acid molecules encoding **amino acid sequences of SEQ ID Nos. 188-374**, which are each distinct nucleic acid coding sequences which encode specific and unique polypeptides. As such, each nucleic acid does not overlap in scope with the others, are not obvious variants, and have materially different functions. Therefore, the search for each nucleic acid sequence is not co-

extensive and it would place an undue burden on the examiner to search and examine all of these inventions together. **Applicants must elect one specific nucleotide SEQ ID NO. encoding a corresponding polypeptide sequence.**

MPEP 1893.03(d) states:

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821

Species restriction

Should **XI** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) **a second composition** comprising a different anti-cancer agent, an agent effective in treating an immune disease, an agent effective in treating a metabolic disease or an agent effective in treating a degenerative disease as recited in claims 70, 74, 76 and 78 selected from one of the following active agents:

monoclonal antibody, chemotherapeutic agents, other polypeptides

The species are independent or distinct because there are methods comprising **compositions** having different chemical structures, physical properties, and biological functions as a result of treating a tumor, an immune disease, a metabolic disease and a degenerative disease differ in etiologies and therapeutic end points requiring different active agents as these disorders are regulated by different genes. For example, a composition for the treatment of a neurodegenerative disorder comprising monoclonal antibodies would not necessary treat a cancer which may need chemotherapeutic agents as different conditions and genes generate these two diseases. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 8 and 70 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633